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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,471	01/30/2004	Michele Cargill	CL001505	6499

25748 7590 07/26/2006

CELERA GENOMICS
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EXAMINER	
KAPUSHOC, STEPHEN THOMAS	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/767,471	CARGILL ET AL.	
	Examiner	Art Unit	
	Stephen Kapushoc	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8 and 23-24, drawn to a method for identifying an individual who has an altered risk of developing an autoimmune disease using nucleic acid based methods to detect SNPs, classified in class 435, subclass 6.

II. Claims 9-11, 15-22, drawn to nucleic acids, classified in class 536, subclass 23.1.

III. Claim 12, drawn to polypeptides, classified in class 530, subclass 300.

IV. Claims 13-14, drawn to antibodies, classified in class 530, subclass 387.1.

V. Claim 25, drawn to methods for detecting polypeptides, classifiable in class 435, subclass 7.1.

VI. Claim 26, drawn to a method for screening therapeutic agents, classified in class 436, subclass 501.

Requirements for further restriction:

If Applicants elect to prosecute the invention or Group I, then applicants shall further select a single particular SEQ ID NO: from SEQ ID NOs:1-669, 1339-49,582 (as recited in claim 1). The claims will only be examined in so far as they require the selected SEQ ID NO; claim 7 will be examined only if the selected SEQ ID NO: is present in Table 6. Applicant shall further select a particular autoimmune disease from

the group consisting of rheumatoid arthritis, type I diabetes, multiple sclerosis, systemic lupus erytematosus, inflammatory bowel disease, psoriasis, thyroiditis, celiac disease, pernicious anemia, asthma, vitiligo, glomerulonephritis, Graves' disease, myocarditis, Sjorgran disease, and primary systemic vasculitis. Claims that recite particular specific autoimmune diseases will only be examined insofar as they require the elected particular autoimmune disease; claims not requiring the elected autoimmune disease will be withdrawn.

If Applicants elect to prosecute the invention or Group II, then applicants shall further select: (i) a single particular SEQ ID NO: from SEQ ID NOs: 1-669, 1339-49,582 (as recited in claim 9) for the examination of claims 9, 10, and 15-21; (ii) a single particular polypeptide sequence from SEQ ID NOs:670-1338 for the examination of claim 11; and (iii) a single SEQ ID NO selected from SEQ ID NOs:49,583-50,230 (as recited in claim 21). The SNP SEQ ID NO selected for (i) should be consonant with the polypeptide SEQ ID NO selected for (ii) and the allele specific primer selected in (iii).

If Applicants elect to prosecute the invention of Group III, IV, or VI then applicants shall further select a single particular SEQ ID NO: from SEQ ID NOs:670-1338 (as recited in claim 12) for examination.

If Applicants elect to prosecute the invention or Group V, then applicants shall further select a single particular SEQ ID NO: from SEQ ID NOs: 1-669, 1339-49,582 (as recited in claim 25).

For any selection as required by the Requirement for Further Restriction, Applicants shall provide a basis for the selection, and point to the portion of the specification that provides support for the selection. Claims of the elected group will only be examined in so far as they require the selected SEQ ID NO. Particularly for claims which refer to Tables (e.g. claims 5 and 10) applicant is requested to point out where in the specification there is basis and support for any selection as required by the Requirement for Further Restriction.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the nucleic acids of group II can be used in methods other than detecting an altered risk cardiovascular disorder. For example, the nucleic acids may be used as templates for the amplification of an insert for an expression vector, or as probes to screen a plasmid library for a particular insert.

3. Invention I is unrelated to the products of inventions III and IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and §

806.06). In the instant case, the method of invention I neither recites nor requires the polypeptides on invention III or the antibodies of invention IV.

4. Invention I is unrelated to the methods of inventions V and VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the method of invention I neither recites nor requires the methods of the invention of group V (variant polypeptide detection) or group VI (screening of therapeutic agents).

5. The inventions of groups II, III, IV are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of Group II is composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix. The polypeptide of Group III is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). Although the polynucleotides and polypeptides are related as the claimed polynucleotides are asserted to encode the claimed polypeptides, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein as evidenced by the methods of at least group I. The antibody of Group IV is also composed of amino acids linked in peptide bonds and arranged spatially in a specific tertiary structure that allows

that antibody to specifically bind to particular regions (i.e. epitopes) of the encoded polypeptides. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) are associated via disulfide bonds into a Y-shaped symmetric dimer. Furthermore, the products of Group II, III, and IV can be used in materially different processes, for example, the DNA of Group II can be used in hybridization assays, the antibody of Group IV can be used in immunoassay, the polypeptide of Group III can be used to make a fusion protein with an enzymatic function. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups II, III, and IV are patentably distinct from each other.

6. Invention II is unrelated to the methods of inventions V and VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the inventions of group V (variant polypeptide detection) or group VI (screening of therapeutic agents) neither recite nor require the method the nucleic acids of the invention of group II.

7. Inventions III and IV are related as products and processes of use the inventions of groups V and VI. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the polypeptides of group III and the antibodies of group IV can be used

in methods other than the inventions of group V (variant polypeptide detection), group VI (screening of therapeutic agents). For example, the polypeptides may be used in *in vitro* assays of protein activity, and the antibodies may be used to neutralize the activity of an expressed polypeptide.

8. Invention V is unrelated to the methods of invention VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the methods of the invention of group V (variant polypeptide detection) and group VI (screening of therapeutic agents) are methods to accomplish the different goals of either protein detection (group V) or therapeutic identification (group VI).

9. Regarding the requirement for further restriction among the various SEQ ID NOs, the different genes are patentably and structurally distinct in that they are composed of unique polynucleotide and polypeptide sequences. Additionally, because the sequences are unique, a reference against one would not necessarily be a reference against any others; therefore each gene, or any particular combination of genes, would require a separate search. Regarding the requirement for Restriction among the different autoimmune disease, the various diseases a patentably distinct because the have different causes and different physiological effects that require distinct treatment regimens.

10. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-VI require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain

dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen Kapushoc
Art Unit 1634

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER